GOVERNMENT OF INDIA
AYURVEDA,YOGA & NATUROPATHY,UNANI,SIDDHA AND HOMEOPATHY (AYUSH)
LOK SABHA

UNSTARRED QUESTION NO:2849
ANSWERED ON:02.12.2016
Quality Control of Ayurvedic Medicines
Natterjee Shri J. Jayasingh Thiyagaraj;Singh Shri Parvesh Sahib

Will the Minister of AYURVEDA,YOGA & NATUROPATHY,UNANI,SIDDHA AND HOMEOPATHY (AYUSH) be pleased to state:

Will the Minister of AYURVEDA, YOGA AND NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (AYUSH) be pleased to state:

(a) whether the Government has taken any steps in order to ensure nation wide quality control of ayurvedic medicines;

(b) if so, the details thereof and if not, the reasons therefor;

(c) whether certain medicines developed by the Central Council of Research in Ayurvedic Sciences have been embroiled in a controversy as to misleading advertisements in the recent past and if so, the details thereof; and

(d) whether the Government has issued a draft notification related to ban on advertisements for products from the Indian traditional medicine category, if so, the details thereof?

Answer

ANSWER
THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYURVEDA,
YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY
(SHRI SHRIPAD YESSO NAIK)
(a) & b): Regulatory provisions for Ayurvedic medicines are in place under the Drugs and Cosmetics Act, 1940, which is a Central Act applicable throughout the country. Under this Act, Rules 151 to 159 of the Drugs and Cosmetics Rules, 1945 have specific regulatory provisions for grant of license to manufacture Ayurvedic medicines and ensure their safety, quality and standards by enforcing Good Manufacturing Practices. The standards of Ayurvedic drugs and their shelf life or date of expiry are prescribed in the Drugs and Cosmetics Rules, 1945 and Rule 158-B specifically prescribes the requirement of proof of safety and effectiveness of various categories of Ayurvedic drugs. Compliance to Good Manufacturing Practices (GMP) and submission of evidence of safety and effectiveness are required for obtaining license to manufacture Ayurvedic medicines. Need-based regulatory amendments for imposing effective quality control of Ayurvedic medicines are made in consultation with the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board following a stipulated procedure. Central Government has published Ayurvedic pharmacopoeia in two parts containing quality standards of 645 single Ayurvedic drugs and 202 Ayurvedic compound formulations. Ministry of AYUSH also provides financial support and guidance to the States for quality control activities related to Ayurvedic drugs and a statutory body in the name of Ayurvedic, Siddha and Unani Drugs Consultative Committee is constituted of members from all States and Central Government to advise in the matters of securing uniformity throughout India in the administration of Drugs & Cosmetics Act, 1940 pertaining to Ayurvedic, Siddha and Unani drugs. In order to facilitate emerging trade and export opportunities for Ayurvedic medicines, voluntary quality certification system is administered by Drugs Controller General of India in accordance with the WHO-GMP and COPP guidelines and by Quality Council of India for granting AYUSH Standard Mark and AYUSH Premium Mark to the eligible products.

(c): An anti-diabetic Ayurvedic formulation, AYUSH-82 for management of Type II Diabetes has developed by the Central Council for Research in Ayurvedic Sciences (CCRAS) has recently been transferred through National Research Development Council, Department of Scientific and Industrial Research, Ministry of Science & Technology & Earth Sciences, Govt. of India to the interested manufacturers for its commercial manufacturing under proprietary category of Ayurvedic drugs. Complaints about the misleading content of the advertisement of this Ayurvedic drug have been forwarded to the concerned State Licensing Authorities for necessary action in accordance with the provisions of Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and Drugs & Cosmetics Act, 1940 and rules thereunder.

(d): Notification of the draft rules for prohibition of misleading advertisements of Ayurveda, Siddha and Unani drugs was issued in the Official Gazette vide GSR No. 396(E) dated 4th April, 2016 to amend the Drugs and Cosmetics Rules, 1945. Copy of the notification providing relevant details is annexed. Comments of the stakeholders and drug manufacturers have been received on the proposed rules.
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